Kiniksa Pharmaceuticals and Huadong Medicine Announce Strategic Collaboration

February 22, 2022

– Collaboration includes rights to develop and commercialize ARCALYST® and mavrilimumab in the Asia Pacific Region (excluding Japan) –

– Kiniksa to receive $22 million upfront; eligible to receive development and commercial milestone payments and tiered royalties –

HAMILTON, Bermuda, Feb. 22, 2022 (GLOBE NEWSWIRE) -- Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) (Kiniksa), a biopharmaceutical company with a portfolio of assets designed to modulate immunological pathways across a spectrum of diseases, and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd. (Huadong Medicine), today announced a strategic collaboration to develop and commercialize Kiniksa's ARCALYST ® and mavrilimumab in the Asia Pacific Region.

"This collaboration aims to bring Kiniksa's therapeutics to patients in the Asia Pacific Region suffering from severe autoimmune and inflammatory diseases. With extensive regional experience, proven development and regulatory execution, and deep relationships with a broad network of hospitals and clinics, Huadong Medicine is an ideal partner to help drive value," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "The collaboration also provides non-dilutive capital, cost-sharing, and resources for clinical trials to accelerate our drug development and commercialization efforts."

"Kiniksa is an emerging leader in the development of immune-modulating therapies, for which there is significant unmet need across the Asia Pacific Region," said Liang Lv, Chairman and CEO of Huadong Medicine. "In addition to ARCALYST, the first and only FDA-approved treatment for recurrent pericarditis, the compelling clinical data generated to-date for mavrilimumab provide foundational support for development across a range of underserved diseases. We look forward to working closely with Kiniksa to leverage our clinical, regulatory, and commercial capabilities in the Asia Pacific Region."

Under the terms of the collaboration, Kiniksa will receive $22 million upfront and is eligible to receive up to approximately $640 million in specified development, regulatory and sales-based milestones. Kiniksa is also eligible to receive tiered royalties ranging from the low-teens to the low-twenties on annual net sales. Huadong Medicine will obtain exclusive rights and responsibility for the development and commercialization of ARCALYST and mavrilimumab in the Asia Pacific Region including Greater China, South Korea, Australia, and 18 other countries, but excluding Japan. Kiniksa will otherwise retain all existing development and commercialization rights for both assets.

About Kiniksa
Kiniksa is a biopharmaceutical company focused on discovering, acquiring, developing, and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need. Kiniksa's portfolio assets, ARCALYST, mavrilimumab, vixarelimab and KPL-404, are based on strong biologic rationale or validated mechanisms, target underserved conditions, and offer the potential for differentiation. These assets are designed to modulate immunological pathways across a spectrum of diseases. For more information, please visit www.kiniksa.com.

About ARCALYST
ARCALYST is a weekly, subcutaneously injected recombinant dimeric fusion protein that blocks interleukin-1 alpha (IL-1α) and interleukin-1 beta (IL-1β) signaling. ARCALYST was discovered by Regeneron and is approved by the U.S. Food and Drug Administration (FDA) for recurrent pericarditis, cryopyrin-associated periodic syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome, and deficiency of IL-1 receptor antagonist (DIRA). The FDA granted Breakthrough Therapy designation to ARCALYST for the treatment of recurrent pericarditis in 2019 and Orphan Drug designation to ARCALYST for the treatment of pericarditis in 2020. The European Commission granted Orphan Drug Designation to ARCALYST for the treatment of idiopathic pericarditis in 2020.

IMPORTANT SAFETY INFORMATION ABOUT ARCALYST

- ARCALYST may affect your immune system and can lower the ability of your immune system to fight infections. Serious infections, including life-threatening infections and death, have happened in patients taking ARCALYST. If you have any signs of an infection, call your doctor right away. Treatment with ARCALYST should be stopped if you get a serious infection. You should not begin treatment with ARCALYST if you have an infection or have infections that keep coming back (chronic infection).
- While taking ARCALYST, do not take other medicines that block interleukin-1, such as Kineret® (anakinra), or medicines that block tumor necrosis factor, such as Enbrel® (etanercept), Humira® (adalimumab), or Remicade® (infliximab), as this may increase your risk of getting a serious infection.
- Talk with your doctor about your vaccine history. Ask your doctor whether you should receive any vaccines before you begin treatment with ARCALYST.
- Medicines that affect the immune system may increase the risk of getting cancer.
- Stop taking ARCALYST and call your doctor or get emergency care right away if you have any symptoms of an allergic reaction.

- Your doctor will do blood tests to check for changes in your blood cholesterol and triglycerides.
- Common side effects include injection-site reactions (which may include pain, redness, swelling, itching, bruising, lumps, inflammation, skin rash, blisters, warmth, and bleeding at the injection site), upper respiratory tract infections, joint and muscle aches, rash, ear infection, sore throat, and runny nose.

For more information about ARCALYST, talk to your doctor and see the Product Information.

About Mavrilimumab
Mavrilimumab is an investigational fully human monoclonal antibody that blocks activity of granulocyte macrophage colony stimulating factor (GM-CSF) by specifically binding to the alpha subunit of the GM-CSF receptor (GM-CSFRα). Phase 2 clinical trials of mavrilimumab in rheumatoid arthritis and giant cell arteritis achieved their primary and secondary endpoints with statistical significance.

About Huadong Medicine
Huadong Medicine Co., Ltd. (SZ.000963) is a leading Chinese pharmaceutical company based in Hangzhou, China. Founded in 1993, Huadong Medicine has fully integrated R&D, manufacturing, distribution, sales, and marketing capabilities. Huadong Medicine's product portfolio and pipeline are specialized in oncology, immunology, nephrology, and diabetes. The company has 11,000 employees and one of the most extensive commercial coverage and marketing capabilities in China. 'Patient Centered, Science Driven' is Huadong Medicine's value. For additional information, please visit www.eastchinapharm.com/en.

Kiniksa Forward Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these identifying words. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, statements regarding the multi-product collaboration between Kiniksa and Huadong Medicine, including anticipated milestone and royalty payments under the collaboration; expectations regarding Kiniksa’s ability to expand its programs for ARCALYST and mavrilimumab globally and in the licensed territory; and statements regarding Kiniksa’s efforts to bring multiple therapeutics to patients suffering from severe autoimmune and inflammatory diseases globally and in the licensed territory.

These forward-looking statements are based on management’s current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including without limitation, the following: delays or difficulty in enrollment of patients in, and activation or continuation of sites for, our clinical trials; delays or difficulty in completing our clinical trials as originally designed; potential for changes between final data and any preliminary, interim, top-line or other data from clinical trials; our inability to replicate results from our earlier clinical trials or studies; impact of additional data from us or other companies, including the potential for our data to produce negative, inconclusive or commercially uncompetitive results; potential undesirable side effects caused by our products and product candidates; our inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities; potential for applicable regulatory authorities to not accept our filings, delay or deny approval of any of our product candidates or require additional data or trials to support approval; inability to successfully execute on our commercial strategy for ARCALYST; our reliance on third parties as the sole source of supply of the drug substance and drug product used in our products and product candidates; our reliance on Regeneron as the sole manufacturer of ARCALYST; raw materials, important ancillary products and drug substance and/or drug product shortages; our reliance on third parties to conduct research, clinical trials, and/or certain regulatory activities for our product candidates; complications in coordinating requirements, regulations and guidelines of regulatory authorities across jurisdictions for our clinical trials; the impact of the COVID-19 pandemic and measures taken in response to the pandemic on our business and operations as well as the business and operations of our manufacturers, CROs upon whom we rely to conduct our clinical trials, and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities; changes in our operating plan and funding requirements; and existing or new competition.

These and other important factors discussed in our filings with the U.S. Securities and Exchange Commission (the “SEC”), including under the caption “Risk Factors” contained therein, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. Except as required by law, we disclaim any intention or obligation to update or revise any forward-looking statements. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

ARCALYST® is a registered trademark of Regeneron Pharmaceuticals, Inc. All other trademarks are the property of their respective owners.

Every Second Counts!®

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